

## PATENT

**REMARKS**

In the Office Action, claims 1, 3-5, 19, and 38 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,714,823 to De Lurgio et al.

In the Office Action, claims 7 and 21 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,714,823 to De Lurgio et al. as applied to claims 5 and 19 above, and further in view of U.S. Patent No. 5,746,701 to Noone.

In the Office Action, claims 39 and 40 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,714,823 to De Lurgio et al. as applied to claims 1 and 19 above.

Following is a discussion of the patentability of each of the pending claims.

**Independent Claim 1**

Claim 1 recites an implantable stimulation lead system comprising a lead and a device dimensioned for insertion within the lead. The lead includes a lead body dimensioned for placement inside the coronary sinus region. The lead body has at least one electrode positioned at a distal end of the lead body, and the distal end of the lead body includes a distal tip. The lead further has a lumen extending the length of the lead and communicating with an aperture in the distal tip. The device is dimensioned for insertion within the lumen, and the device includes a main body and a flexible distal portion secured to a distal extremity of the main body. The main body has a length such that, with the main body of the device substantially completely advanced within the lead, the flexible distal portion of the device projects distally from the aperture in the distal tip of the lead body. The combined length of the main body of the device and the flexible portion of the device is slightly longer than the lead body.

As stated previously in the Response dated January 26, 2005, the De Lurgio et al. reference discloses an implantable stimulation lead system comprising a lead (32) and a stylet (42) (see Figures 3 and 4). The stylet, with its attached distal coil (44), is inserted into a central channel of the lead so that the distal coil protrudes through a

## PATENT

valve (38) and out of a body (34) of the lead. The specification states that the amount of protrusion can be adjusted to the desired length.

The Examiner states that the first embodiment (see Figures 1 and 2) of the De Lurgio et al. reference discloses a combined length of the main body and the flexible distal portion is slightly longer than the lead body. It is noted that the first embodiment is not directed to a system comprising a lead and a device dimensioned for insertion within the lumen of the lead, wherein the device includes a flexible distal portion. The first embodiment comprises a floppy coil (22) affixed to a distal end of a pacing lead (20). A conventional stylet (10) is inserted into the pacing lead for steering, but does not extend into the floppy coil (see Figure 1 and column 3, lines 9-14). The floppy coil remains after placement of the pacing because it is an integral part of the pacing lead. As such, the first embodiment of the De Lurgio et al. reference discloses a flexible distal portion secured to the lead whereas claim 1 of the present application recites a flexible distal portion secured to the device which is dimensioned for insertion within the lumen of the lead.

As stated previously in the Response dated January 26, 2005, the Noone reference discloses a guidewire which achieves flexibility in the distal portion by having a plurality of notches cut into a body of the guidewire. In an embodiment illustrated in Figure 10, the guidewire (100) comprises a main body (101) and a flexible distal portion (103 and 106). However, nowhere does the Noone reference disclose or suggest that the combined length of the main body of the guidewire and the flexible distal portion of the guidewire is slightly longer than a lead that is intended to be placed thereby. It appears that the guidewire of the Noone reference is most likely substantially longer than a lead that is intended to be placed thereby.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

## PATENT

Dependent Claims 2-18, 38, and 39

Claims 2-18, 38, and 39 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 19

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that amended claim 19 is in condition for allowance.

Dependent Claims 20-25 and 40

Claims 20-25 and 40 depend from claim 19 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

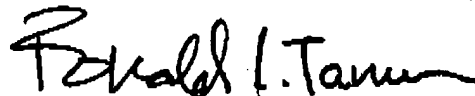
CONCLUSION

In light of the above remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

5/3/05

Date



Ronald S. Tamura, Reg. No. 43,179  
Patent Attorney for Applicant

**CUSTOMER NUMBER: 36802**